K110392

DEC 14 2011

510(k) Summary

>> 510(k) Summary as required by section 807.92(c)

Submission Applicant: Date: 12/01/11

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Establishment Registration Number:
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Trade name:
PSM LOMAS / BENEFIT Screws

Common name:
Root-form endosseous dental implants, Orthodontic endosseous dental implant

Classfication name: Endosseous dental implant, Dental -21 CFR 872.3640

Product Code: OAT

Predicate Devices:
- Lin/Liou Orthodontic Mini Anchor System (LOMAS) ***K042345*** and Lin/Liou Orthodontic Mini Anchor System (LOMAS) (Sterile) ***K050257*** - manufactured by: Mondeal Medical Systems GmbH.

- Syntec Orthodontic Mini Screws ***K090476*** manufactured by Syntec Scientific Corporation

- IMTEC Sendax MDI ORTHO ***K023067*** made by IMTEC Corporation

- MDI ORTHO ***K042289*** made by IMTEC Corporation

Description of the Device:

The PSM LOMAS / BENEFIT Screws are made of Titanium alloy. The bone screws are designed to be used transmucosally for osseous orthodontic anchorage. They are used as Temporary Anchorage Devices (TAD) for orthodontic treatments. The LOMAS screws (Ø1.5 mm and 2.0 mm), as well as the BENEFIT screws (Ø2.0mm and 2.3mm) come in two diameters and all screws come in five lengths (7 mm, 9 mm, 11 mm, 13 mm, and 15 mm). The screws are divided in five groups of screws, LOMAS Standard, LOMAS Hook, LOMAS Quattro, LOMAS Quattro V and BENEFIT Screws. The range of products is providing flexibility for specific orthodontic applications.
The screws consist of either three or four components: head, platform, body (thread) or moreover neck.

Indications for Use:

The PSM LOMAS / BENEFIT Screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. Screws are intended for single use only.

Technological characteristics compared to the Predicate Devices:

The PSM LOMAS / BENEFIT Screws are similiar to the Predicate Devices *Lin/Liou Orthodontic Mini Anchor System (LOMAS),* Syntec *Orthodontic Mini Screws, and* IMTEC MDI ORTHO in terms of technical characteristics, Indications for Use, material, target population, performance, safety, effectiveness and biocompatibility characteristics. Moreover the design and sizes of the new device are strongly identical with the predicates. Therefore the PSM product can be deemed substantially equivalent for its indicated use.

Performance data:

On the PSM LOMAS / BENEFIT Screws were performed Breakage and Fatigue Tests, Material Tests, Validation Tests of sterile barrier system and packaging system, Sterilization Validation Tests, Microbiological Test for determination of microorganisms, and several Clinical Justifications and Studies.

Summary

The information submitted demonstrates the PSM LOMAS/BENEFIT Screws are substantially equivalent to predicate orthodontic anchorage screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

PSM MEDICAL SOLUTIONS
C/O Ms. Andrea Pecsi
THINK!
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DEC 14 2011

Re: K110392
Trade/Device Name: PSM LOMAS / BENEFIT Screws
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: December 5, 2011
Received: December 8, 2011

Dear Ms. Pecsi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110392

Device Name:
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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